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EXAMINER				
CLARK, SARA E				
ART UNIT		PAPER NUMBER		
1612				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Patent_Mail@arentfox.com

Office Action Summary

Application No.

10/552,444

Applicant(s)

ORTE ET AL.

Examiner

SARA E. CLARK

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 17-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-US)
Paper No(s)/Mail Date 10/7/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

NON-FINAL REJECTION

This application is a 35 U.S.C. 371 (national stage) application of PCT/FI04/00226, filed 4/13/2004, which claims benefit of priority to Finnish application no. 20030540, filed 4/10/2003. Claims 1-29, as amended, are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-16) in the reply filed on 6/24/2009 is acknowledged. The traversal is on the ground(s) that PCT Rule 13 entitles Applicant to examination of a product, process of making, and process of using. This is not found persuasive because the groups must share a special technical feature that is not known in the prior art. Where there is no shared special technical feature that distinguishes the inventions over the prior art, by definition, unity of invention is lacking. See 37 CFR 1.475(a). Applicant further contends that the search and examination burden would not be undue. While this consideration is relevant with regard to domestic applications filed under 35 USC §111(a), this is not a factor in national stage applications filed under 35 USC §371. See MPEP 1893.03(d).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 17-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/24/2009.

Priority

3. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

4. The information disclosure statement filed on 10/7/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each document listed that is not in the English language, specifically, EP 1179535 and EP 1179536. It has been placed in the application file and English-language references have been considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites the limitation "the hydrolysing and alkylating composition" in the first to second lines of claim 12. There is insufficient antecedent

basis for this limitation in claim 1, from which claim 12 depends, which does not recite a "hydrolysing and alkylating composition."

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schul et al. (WO01/72136, published 10/4/2001), in view of Bonakdar et al. (PG Pub. 2002/0082434, published 6/27/2002), both provided by Applicant on the IDS dated 10/7/2005.

Schul et al. disclose a method of preparing sterol ester compositions comprising the steps of (a) providing fatty acid esters, (b) preparing a sterol-ester mixture, (c) refining the sterol-ester mixture, (d) evaporating and stripping the sterol-ester mixture, and (e) fractionating the sterol-ester mixture to obtain a sterol ester composition (p. 5, lines 13-20). Specifically, Schul et al. disclose reacting the sterols with lower alkyl fatty acid esters in the presence of a basic esterification catalyst, such as sodium methoxide (NaOCH_3) to form a crude sterol ester reaction mixture, yielding a sterol fatty acid ester-rich composition containing less than about 3% free sterols (p. 8, lines 8-26; Example 2). This procedure corresponds to steps (a), (b), and (d) as recited by claims 1-16; the

esterification catalyst NaOCH_3 as recited by claim 9; and a yield of at least 90% w/w sterol fatty acid esters as recited by claim 16.

Further, Schul et al. teach that an initial heterogeneous crude reaction mixture comprises from about 40% to about 60% w/w sterol; from about 40% to about 60% w/w fatty acid alkyl esters; and from about 0.1% to about 3% w/w basic catalyst component, more of which can be added toward the end of the reaction, which is suitably an alkali metal hydroxide (e.g., potassium hydroxide, KOH) or, most preferred, potassium or sodium methoxide in a methanol solution (p. 9, lines 14-23). This corresponds to the addition of at least one fatty acid alkyl ester, as recited by claim 2; the hydrolyzation catalyst KOH and the alkylating component methanol as recited by claim 8; the molar ratio of sterols and fatty acid methyl esters (1:0.9-2.1) as recited by claim 14, and the addition of hydrolyzation catalyst KOH and alkylating component methanol when the esterification reaction is complete or mainly complete, as recited by claim 15.

Schul et al. also disclose steps to purify the sterol fatty acid ester-rich composition, which include the addition of water to destroy the catalyst (e.g., KOH or NaOCH_3) then centrifugation to remove basic catalyst and soap (Na^+ or K^+ salts of fatty acids hydrolyzed by the basic catalyst), followed by bleaching with the use of adsorbents such as bleaching earth, silica gel, or activated charcoal; and evaporating and stripping the sterol fatty acid ester-rich composition by removing unwanted materials such as free fatty acids, excess fatty acid ester reactant. (p. 10, line 5 to p. 11, line 9; Example 2), corresponding to the purification step by bleaching, filtration, and/or deodorization as recited by claim 13. In addition, Schul et al. disclose purifying the sterol

fatty acid ester-rich composition as the reaction proceeds by adding methanol and NaOCH_3 , then drawing off the glycerin (a.k.a. glycerol), repeating, then collecting the fatty acid (canola oil) methyl ester distillate (Example 1), corresponding to the removal of glycerol as recited by claim 3, and to the separation of fatty acid alkyl ester from the mixture as recited by claim 5.

However, Schul et al. do not explicitly disclose step (c) as recited by claim 1, in which a hydrolyzation catalyst (e.g., KOH) and an alkylating component (e.g., methanol) are added to hydrolyze glycerides present in the reaction mixture to produce fatty acid alkyl esters and glycerol. Schul et al. also do not teach step (d1) as recited by claim 4, in which the esterification and/or hydrolyzation catalyst (e.g., KOH or NaOCH_3) is removed with the glycerol, or step (d2) as recited by claim 6, in which separated fatty acid alkyl esters are fed back into the reaction mixture. Schul et al. do not disclose pre-mixing the hydrolyzation catalyst (e.g., KOH) and an alkylating component (e.g., methanol) as recited by claim 7, or the proportions of hydrolyzation catalyst (e.g., KOH) and alkylating component (e.g., methanol) as recited by claims 10-12.

Bonakdar et al. disclose processes for the production of free sterols from sterol fatty acid esters; that is, essentially the reverse procedure from that taught by Schul et al. Bonakdar et al. note that methods of obtaining free sterols are known in which a residue from the distillation of methyl esters, consisting of glycerides, sterols, and sterol esters, is transesterified with methanol in the presence of alkaline catalysts; however, there are disadvantages which Bonakdar et al. seek to remedy, including the utilization of residues from the distillation of transesterified oils more economically (para. 0002). In

particular, Bonakdar et al. (paras. 0004-0006) disclose a process directed to the use of transesterification mechanisms for the production of sterols from distillation residues, comprising the steps of, *inter alia*,

- transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst to form fatty acid alkyl esters and glycerol, and
- removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters.

Specifically, the mono-, di-, and triglycerides are reacted with a lower alcohol in the presence of a basic catalyst to form fatty acid esters; then, after removal of excess alcohol, transesterification catalyst, and glycerol, the fatty acid esters are distilled, resulting in concentration of the sterol esters at the bottom of the column (para. 0008). Only a small amount of free sterols is formed. Methanol is preferably used as the alcohol, and is added in a quantity of 5 to 40% w/w (paras. 0011-0012). 30% methanolic sodium methylate solution is the preferred basic esterification catalyst and is used in a quantity of preferably 0.5 to 1.8% w/w (para. 0013). This corresponds to step (c) as recited by claims 1-16, in which a hydrolyzation catalyst (e.g., a basic catalyst such as KOH) and an alkylating component (e.g., a lower alcohol such as methanol) are added to hydrolyze glycerides present in the reaction mixture to produce fatty acid alkyl (methyl) esters and glycerol. In addition, Bonakdar et al. (para. 0007) teach that the basic transesterification catalyst and the glycerol are removed together, as recited by claim 4; and the fatty acid alkyl ester is distilled off from the mixture, as recited by claim

5. Bonakdar et al. also disclose that, to increase the product yield, part of the mother liquor is recycled (para. 0035), corresponding to the recycling step recited by claim 6.

While the references do not explicitly teach the proportions of hydrolyzation catalyst (e.g., KOH) and alkylating component (e.g., methanol) as recited by claims 10-12, it is *prima facie* obvious to one of ordinary skill in the art to optimize the proportions of known reactants in known processes by routine experimentation. As recognized by MPEP § 2144.05,

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In summary, one of ordinary skill in the art would have been motivated to improve the method of preparing a composition rich in sterol fatty acid esters comprising steps (a), (b), and (d) as taught by Schul et al. by incorporating step (c) as taught by Bonakdar et al., because more efficient and economical utilization of reagents and by-products is always an objective in chemical processes. Schul et al. disclose the conversion of free sterols into sterol fatty acid esters, while Bonakdar et al. disclose the conversion of sterol fatty acid esters into free sterols, overlapping to the extent that the same reagents and intermediate steps are employed, such that modifications to resulting in incremental improvements are known in the art. This is evidenced by, for example, Flickinger et al. (WO02/60916, provided by Applicant on the IDS dated 10/7/2005) which discloses substantially the same process as Schul et al., plus the step of recirculating the reaction

mixture through a molecular distillation unit to increase the concentration of the sterol fatty acid ester-rich fraction (Example 3).

As noted in US Pat. 6,800,317 (col. 13, lines 1-12), which also claims methods of preparing sterol fatty acid ester compositions,

It is obvious to persons skilled in the art that sterol and/or stanol esters with fatty acid compositions specified in this invention also can be obtained by esterification with fatty acid alcohol esters with the specified fatty acid composition produced by any method of prior art. Furthermore, it is obvious that sterol and/or stanol esters according to the invention can be obtained via any esterification process, such as direct, preferentially catalytic esterification, transesterification or enzyme facilitated esterification.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the process disclosed Schul et al. by incorporating steps taught by Bonakdar et al. with a reasonable expectation of success, because both processes employ the same reagents and intermediates, and combining known steps in known processes to optimize yield and efficiency while minimizing energy, costs, and by-products and is a standard goal in industrial chemistry.

Conclusion

9. Claims 1-16 are rejected.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Frederick Krass, can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARA E. CLARK/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612